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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,782	04/15/2004	Bernardus Petrus Hubertus Pecters	2183-4646.2US	7153

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER

HURT, SHARON L

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/824,782		PEETERS ET AL.	
	Examiner		Art Unit	
	Sharon Hurt		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1-16 are pending. Claims 6-8 are withdrawn. Claims 1-5 and 9-16 are under examination on the merits

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-5 and 9-16 under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (Journal of Virology, Apr. 1990, Vol. 64, No. 4, pages 1441-1450) is **maintained**. Applicant's arguments filed November 16, 2006 have been fully considered but they are not persuasive. Applicant argues that Taylor discloses the exact opposite of the claimed invention. Applicant also argues that the claims disclose a negative marker from a deletion virus.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Negative marker) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claimed invention is of record. The claims are drawn to a method of distinguishing if an animal is infected with wild-type Newcastle Disease virus (NDV) or has been vaccinated

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with an unmodified mesogenic or lentogenic NDV strain or not vaccinated, wherein the vaccine comprises an infectious copy of avian-paramyxovirus encoding viral proteins having a modification relative to wild-type or unmodified mesogenic or lentogenic NDV strain and analyzing for the presence of antibodies directed against an epitope or marker expressed by wild-type or unmodified NDV, but not by said vaccine, wherein the epitope is a hemagglutinin-neuraminidase (HN) or fusion protein (F) of NDV.

The teachings of Taylor et al. (hereinafter Taylor) are of record. Taylor teaches a method of detecting NDV F protein in samples from chickens that were vaccinated with lentogenic or mesogenic strains of NDV and infected with wild-type NDV (page 1446 and 1448, Discussion). Taylor also teaches that cleavage of the F protein is important in determining the pathogenicity of the NDV strain and the amino acid sequence at the cleavage site is therefore critical in determining the virulence of the NDV strain (page 1444, 2nd column). Taylor further teaches that a comparison of the sequence differences can differentiate the avirulent strains from the virulent strains therefore distinguishing the vaccinated from the unvaccinated chickens and wild-type NDV from unmodified or lentogenic strains of NDV (page 1448). Taylor meets all the limitation of the claimed invention.

Applicant is arguing the claims require a negative marker from a deletion mutant and that the vector of Taylor is the opposite, i.e., a vector in which heterologous nucleic acid from NDV has been inserted. Applicant also argues that the prior art uses a pox vector instead of a paramyxovirus. While it is true that Taylor uses a fowlpox vector to express the NDV antigens, wherein applicant uses a deletion paramyxovirus mutant to express those same antigens, the vector used to express the antigens in the vaccinated animal is irrelevant to the method as is

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presently claimed. Regardless of the actual vector used to express the antigens in the vaccinated animal, a deletion mutant of a paramyxovirus encoding the NDV antigens or a pox virus vector encoding the NDV antigens, the art anticipates the claims because both the present claims and the art teach taking at least one sample, and analyzing the sample for the presence of antibodies directed against an epitope or marker which is expressed by wild type or unmodified NDV but not by the vaccine vector. Furthermore, the vector taught by Taylor meets the limitations of the claims because it is infectious and is at least partly derived from NDV. Therefore, Taylor meets all of the limitations of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

28 February 2007



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